BACKGROUND & OBJECTIVES

- In recent years, an increasing number of oncolgical drugs have been approved for multiple indications. Their clinical value, however, varies across indications, while price is typically uniform. In 2014, 55% of oncolgical drugs had multiple indications and this ratio is expected to grow to 76% in 2020.

Fig. 1: Clinical value by indication

![Graph showing clinical value by indication](image)

Imposing a uniform price on a drug whose clinical value varies across indications is potentially harmful, as it misaligns social and industry incentives. We review the literature to investigate whether there exist indication-specific pricing models (ISP) that can align clinical value and price in each indication and evaluate their pros and cons.

METHODS

- We performed an extensive systematic literature review about multi-indication pricing models worldwide, both in grey and academic sources, including: PubMed, EMA, ISPOR, financial reviews, press releases, Medicare, Medicaid, Veterans Health Administration, Google, Google Scholar, HMO and NICE and AIFA web pages. The retrieved papers were analyzed based on the year, country, type of agreement, its characteristics, and the therapeutic area.

- We discuss the conditions that lead to the possibility of ISPs, types of ISPs, risks and benefits for payers and laboratories, the international experience and some examples of ISPs. We identified the obstacles for implementing ISP and possible solutions. We analyzed the Italian case in detail, as Italy is the country with a higher experience in ISP implementation.

RESULTS

- The analysis showed that there are three types of ISPs: (i) different brand names for each indication, (ii) different discount for each indication, and (iii) a weighted average price, where the price reflects the benefit in each weighted indication by the population covered in each indication.

- Payers and society benefit from multi-indication pricing in that clinical value is aligned to price, fostering incentives of R&D where they are more needed, and minimize the risk of paying a high amount of money in low-value indications. The main cost is due to the administrative burden of keeping the information needed for multi-indication pricing.

- Laboratories benefit from multi-indication pricing in that they erase the risk of price reduction in case new indications are approved. The main downside for laboratories is the need to monitor that hospitals actually use the drug in the indications they pay for.

- The UK, Australia, and Italy have implemented, or have attempted to implement, some form of ISP. The country that most implemented them is Italy.

<table>
<thead>
<tr>
<th>Country</th>
<th>ISP type</th>
<th>Details</th>
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<tbody>
<tr>
<td></td>
<td>Single weighted average price</td>
<td>1) Manufacturers set the prices of medicines freely without regulatory intervention.</td>
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<td></td>
<td>ISP in one indication</td>
<td>1) The UK introduced an optional flexible pricing scheme in the Pharmaceutical Price Regulation Scheme of 2009 (PPRS).</td>
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<td>ISP as different discounts</td>
<td>This mechanism is used for Avastin, for which only the low dosis regimen is reimbursed in lung cancer.</td>
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<td>ISP as different discounts</td>
<td>1) Italy created, within its regulatory body (AIFA), registries of oncological and hematological medicines depending on their indication.</td>
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CONCLUSIONS

Indication-specific pricing is a novel tool in many countries, though Italy already implemented it quite widely. More drugs have multiple indications, so aligning price and value will become more compelling in the next future. We show that their implementation is feasible and no major hurdle impedes it in Spain.

REFERENCES